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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,003	KHARBANDA ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *10-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/17/07; 6/10/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to comply*.

DETAILED ACTION

1. The preliminary amendment filed 24 April 2006 has been entered in full.

Election/Restrictions

2. Applicant's election without traverse of the Invention of Group I, claims 1-9 and SEQ ID Nos:1, 3, 5, 9, 11, 15, 17, 19, 25 and 27 in the reply filed on 31 October 2008 is acknowledged, however upon further consideration and in view of an omission in the previous restriction requirement mailed 8/4/2008, the restriction requirement mailed 8/4/2008 is hereby VACATED in favor of the instant restriction requirement, which corrects the omission.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a MUC1 chimeric polypeptide comprising a MUC1-EC polypeptide and a human immunoglobulin Fc polypeptide or a human albumin polypeptide. In view of this Holgersson et al (WO 04/15057 A2, 8/9/2002, cited on PTO-892 mailed 8/4/2008) reads on the claim. Holgersson et al teach fusion proteins comprising a mucin extracellular polypeptide fused to a human Fc polypeptide. Therefore, the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-9, drawn to a MUC1 chimeric polypeptide comprising a MUC1-EC polypeptide and a human immunoglobulin Fc polypeptide and pharmaceutical compositions comprising such.

Group II, claims 1-3 and 8-9, drawn to a MUC1 chimeric polypeptide comprising a MUC1-EC polypeptide and a human albumin polypeptide and pharmaceutical compositions comprising such.

Group III, claims 10-14, drawn to methods of inhibiting the proliferation of a MUC1-expressing cancer cell, killing a MUC1-expressing cancer cell and treating cancer in a patient comprising administering an effective amount of a MUC1 chimeric polypeptide comprising a MUC1-EC polypeptide and a human immunoglobulin Fc polypeptide.

4. If applicant elects the invention of Group I or II above, restriction to up to ten (10) of the recited MUC1-EC polypeptide sequences is required under 35 U.S.C. 121. Applicant is advised that this restriction also applied to any newly added method claims directed to more than ten (10) MUC1-EC polypeptides.

Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. Applicant(s) must further elect up to ten (10) sequences for examination. It is noted that this is a restriction requirement to a single sequence and NOT a species election requirement.

Applicant should clearly identify X, Y, and Z for the elected claims.

MPEP 803.04 states:

"Polynucleotide molecules defined by their nucleic acid sequence (hereinafter "nucleotide sequences") that encode< different proteins are structurally distinct chemical compounds. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and

distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq."

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

5. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Holgersson et al groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

Inventions of Groups I and II represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects. The chimeric polypeptide of Group I and the chimeric polypeptide of Group II are structurally and chemically different from each other. The polypeptide of group I can be produced as a fusion protein and comprises the Fc region of an immunoglobulin, which can bind Fc receptors and can be used therapeutically (i.e., mediates ADCC), whereas the chimeric polypeptide of Group II does not bind Fc receptors. The polypeptides of Groups I and II are patentably distinct because each is structurally distinct and art on one would not necessarily be art on the others. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups I-II are patentably distinct.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the MUC1 chimeric polypeptide of Group I can be used in a materially different method such as isolation/identification of MUC1 ligands in addition to the materially different therapeutic method of Group III.

6. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;
(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement

will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. During a telephone conversation with Monica De La Paz on 16 January 2009 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-9 and SEQ ID Nos:1, 3, 5, 9, 11, 15, 17, 19, 25 and 27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

9. Claims 1-9 are under consideration to the extent that the MUC1-EC polypeptide of the MUC1-EC-human Fc chimeric protein comprises the sequence of SEQ ID Nos:1, 3, 5, 9, 11, 15, 17, 19, 25 or 27.

Information Disclosure Statement

10. The information disclosure statement (IDS) submitted on 17 October 2007 and 10 June 2008 have been fully considered by the examiner. A signed and initialed copy of each IDS is included with the instant Office Action.

Sequence Requirements

11. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825. The specification at pg. 5, line 22 discloses a sequence that is encompassed by the sequences rules and requires a sequence identifier (SEQ ID

number). Applicants' cooperation is requested in reviewing the entire disclosure for additional sequences to ensure that the application is in sequence compliance.

12. Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply (see attachment).

13. APPLICANT IS GIVEN THE TIME ALLOTED IN THIS OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six-month statutory period. Direct the response to the undersigned.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1, 3, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Holgersson et al (WO 04/15057 A2, 8/9/2002, cited on PTO-892 mailed 8/4/2008).

Holgersson et al teach fusion proteins comprising a mucin extracellular polypeptide, including MUC1, fused to a human Fc polypeptide and pharmaceutical compositions comprising the fusion polypeptide and a pharmaceutically acceptable carrier (see entire document, particularly pp. 8-12, 19-20 and claims). Products of

identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Thus, one of ordinary skill in the art would reasonably conclude that Holgersson's MUC1-EC-Fc fusion proteins also possesses the same structural and functional properties as those of the MUC1-EC-Fc fusion proteins claimed and, therefore, the MUC1-EC-Fc fusion proteins of Holgersson would necessarily bind dermcidin, Y-P30 or PLU-1.

Thus, Holgersson et al anticipate the claims.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holgersson et al (WO 04/15057 A2, 8/9/2002, cited on PTO-892 mailed 8/4/2008) in view of Capon et al (U.S. Patent 5,116,964, issued 5/26/1992) and Wreschner et al (WO 96/03502, published 2/8/1996, IDS reference B5 filed 10/17/2007).

Holgersson et al have been described supra. Holgersson et al also teach that the fusion polypeptide is a multimer or dimer (see pg. 2 and claims). Holgersson et al do not specifically teach wherein the human Fc polypeptide is a human IgG1 or IgG2 polypeptide or wherein the MUC1 chimeric protein is a dimer and the dimer is formed by means of a disulfide bridge between the hinges or wherein the MUC-EC polypeptide comprises SEQ ID NO:1, 3, 5, 9, 11, 15, 17, 19, 25 or 27. These deficiencies are made up for in the teachings of Capon et al and Wreschner et al.

Capon et al teach hybrid immunoglobulins comprising a ligand binding domain fused to the Fc region which prolong the *in vivo* plasma half-life of the ligand binding domain and wherein the fusion proteins are assembled as monomers, hetero- or homodimers or multimers (via disulfide bonds) and the Fc region may comprise the constant regions are selected from IgG1, IgG2, IgG3, IgG4, particularly human IgG1, which resulted in chimeric molecules that were efficiently synthesized and dimerized in the absence of any light chain as well as compositions comprising the ligand binding domain-Fc fusion proteins and a pharmaceutical acceptable carrier (see entire document, particularly cols. 4, 6, 8, 10-14, 29, 31, Fig. 8 and Example 4).

Wreschner et al teach that MUC1 is abundantly expressed in human breast carcinomas and Wreschner et al teach several forms of MUC1, including receptor proteins MUC1/X, MUC1/Y and MUC1/V as well as the extracellular domains and sequences thereof and their administration as soluble MUC1/X, MUC1/Y and MUC1/V to inhibit the binding of MUC1 ligands, thereby limiting the growth of the breast cancer cells (see entire document, particularly pp. 1-4, 11-13, 15 and Figs. 3-6).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a MUC1-hIgG-Fc fusion protein comprising an extracellular domain of MUC1/X, MUC1/Y or MUC1/V fused to the Fc region of a human IgG, particularly hIgG1 as well as pharmaceutical compositions comprising the MUC1-hIgG-Fc fusion protein and a pharmaceutically acceptable carrier for therapeutic benefit of in human breast cancer patients.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced a MUC1-hIgG-Fc fusion protein comprising an extracellular domain of MUC1/X, MUC1/Y or MUC1/V fused to the Fc region of a human IgG, particularly hIgG1 as well as pharmaceutical compositions comprising the MUC1-hIgG-Fc fusion protein and a pharmaceutically acceptable carrier for therapeutic benefit of in human breast cancer patients in view of Holgersson et al and Capon et al and Wreschner et al because Holgersson et al teach fusion proteins, including multimeric or dimeric fusion proteins comprising a mucin extracellular polypeptide, including MUC1, fused to a human Fc polypeptide and pharmaceutical compositions comprising the fusion polypeptide and a pharmaceutically acceptable carrier and Capon et al teach hybrid immunoglobulins comprising a ligand binding domain fused to the Fc region which prolongs the *in vivo* plasma half-life of the ligand binding domain and wherein the fusion proteins are assembled as monomers, hetero- or homodimers or multimers (via disulfide bonds) and the Fc region may comprise the constant regions are selected from IgG1, IgG2, IgG3, IgG4, particularly human IgG1, which results in chimeric molecules that are efficiently synthesized and dimerized in the absence of any light chain as well as compositions comprising the ligand binding domain-Fc fusion proteins and a pharmaceutical acceptable carrier and Wreschner et al teach that MUC1 is abundantly expressed in human breast carcinomas and Wreschner et al teach several forms of MUC1, including receptor proteins MUC1/X, MUC1/Y and MUC1/V as well as the extracellular domains and sequences thereof and their administration as soluble MUC1/X, MUC1/Y and MUC1/V to inhibit the binding of MUC1 ligands, thereby limiting the growth of the breast cancer cells. Therefore, one of ordinary skill in the art would have been motivated to produce MUC1 fusion proteins

comprising the MUC1/X, MUC1/Y or MUC1/V extracellular domain (i.e., comprising the recited MUC-EC sequences) fused to a human IgG Fc region, particularly the human IgG1 Fc region, which was shown to be efficiently synthesized and dimerize in the absence of any light chain, in order to prolong the *in vivo* plasma half-life of the soluble MUC1 extracellular domains for inhibiting the growth of breast cancer cells in human patients. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Sernaker*, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). Thus, it would have been *prima facie* obvious to one skilled in the art to have produced a MUC1-hIgG-Fc fusion protein comprising an extracellular domain of MUC1/X, MUC1/Y or MUC1/V fused to the Fc region of a human IgG, particularly hIgG1 as well as pharmaceutical compositions comprising the MUC1-hIgG-Fc fusion protein and a pharmaceutically acceptable carrier for therapeutic benefit of in human breast cancer patients in view of Holgersson et al and Capon et al and Wreschner et al.

Further, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Thus, one of ordinary skill in the art would reasonably conclude that the MUC1-hIgG-Fc fusion proteins also possesses the same structural and functional properties as those of the MUC1-hIgG-Fc fusion proteins claimed and, therefore, the MUC1-hIgG-Fc fusion protein of Holgersson et al and Capon et al and Wreschner et al would necessarily bind dermcidin, Y-P30 or PLU-1.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

18. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643